

R E M A R K S

Claims 1-11, 13-22, and 24-26 are in the application. Claim 24 has been withdrawn as being drawn to a non-elected invention. In the Office Action, claims 1, 3, 5, 10-11, and 15-20 are objected to because of various alleged informalities. Claims 2, 4, and 15-22 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claims 2-4, 7, 15, 17, 19, and 20 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,840,543 to Hockney et al. ("Hockney"). Claims 5, 16, 18, 21, and 22 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hockney in view of Baneyx et al. (Curr. Opin. Biotech., 1999, 10:411-421). Applicants would like to thank the Examiner for the correct indication that claims 6, 8, 9, 13, and 14 are allowable.

Claims 25 and 26 are new claims. Support for the claims can be found on page 11, third full paragraph of the specification, as originally filed. No new matter is added into the case by the new claims.

Claims 1-6, 10-11, and 13-22 are amended to more particularly point out and distinctly define the presently claimed subject matter, and to provide grammatical corrections. Support for the amendments may be found throughout the specification and claims as originally filed. No new matter is added into the case by the present amendments.

All objections and rejections are respectfully traversed. Reconsideration and favorable action are requested in light of the forgoing amendments and these remarks.

A. The Objections to Claims 1, 3, 5, 10-11, and 15-20 are Moot

Claims 1, 3, 5, 10-11, and 15-20 are objected to due to various alleged informalities, grammatical errors, and non-compliance with the rules regarding sequences. The claims are amended, as suggested in the office action, to be in proper form, thereby overcoming the objections. No new matter is added into the case by the present amendments. Accordingly, applicants hereby respectfully request reconsideration and withdrawal of the objections to claims 1, 3, 5, 10-11, and 15-20, and prompt allowance thereof.

B. Claims 2, 4, and 15-22 are Definite

Claims 2, 4, and 15-22 are said to be indefinite as currently drafted. In this regard, Applicants wish to note that, according to MPEP 2111.01, the words of a claim must be given

their plain and ordinary meaning according to the understanding of those of ordinary skill in the art, unless such meaning is inconsistent with the specification. The specification sets forth on pages 6-8 specific definitions of several terms used throughout this application. In accordance with the MPEP, the terms defined on pages 6-8 are to be understood as defined in the specification.

Also, according to MPEP 2173.02, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim reasonably apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the Larsen claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2.). See also *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles....Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.").

Applicants respectfully submit that the Examiner has failed to discharge the Examiner's burden of showing the terms of the claims lack sufficient clarity under the law. See MPEP 2173.02, which states that the Examiner's focus during examination of claims for compliance

with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the Examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the Examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the Examiner might desire. Accordingly, it is the burden of the Examiner to at least make a *prima facie* showing that the rejected/objected to claim terms lack sufficient clarity under the law.

Claim 2 is rejected as indefinite because the sequence claimed is said to be unclear. However, the individual codons in each of sequence segments I, II, III, and IV which are modified from the native hG-CSF gene sequence are specifically set forth, defined, and enumerated on pages 9-10 of the specification. The Examiner has not shown how one of ordinary skill in the art would be unable to determine the meaning and scope of the limitations in claim 2 as amended, keeping in mind the well known common sense rule that claim terms need not find support *ipsis verbis* in the specification for purposes of section 112. It is sufficient if a person of ordinary skill in the art could determine the meaning and scope of the claim limitation in question with the information provided coupled with what they already know and can reasonably expect to already know from information generally available in the art. It has not been shown that a person having ordinary skill in the art would be unable to do so here with respect to the noted limitations of segments I-IV of claim 2, or for that matter, any of the other limitations said to lack sufficient clarity or definiteness under §112. However, in order to advance the prosecution and to further clarify the claim, the phrase "essentially no change" in claim 2 is amended to recite the replacement of two codons in this sequence segment, as defined on page 10, lines 13-15 of the specification. Accordingly, claim 2 as amended is more than sufficiently definite under 35 U.S.C. §112.

Claims 4 and 19 are amended to clarify the method of quantifying the amount of G-CSF expressed. The amendment is supported by page 6, lines 19-23 of the specification. No new matter is added into the case by the amendment. Accordingly, amended claims 4 and 19 are not indefinite.

Claim 15 is rejected as indefinite for allegedly failing to recite the methods applied to produce the DNA sequence. Claim 15 is amended to enumerate these methods. Support for the amendment may be found on pages 13-14 of the specification. Accordingly, amended claim 15 is plainly not indefinite.

Claim 15 is also rejected as allegedly indefinite for the recitation of "a substantial portion". While this language is acceptably definite under legions of court decisions and USPTO practice, the claim is amended to instead recite "at least a portion", and thus is not indefinite. No new matter is added by the amendment.

Claims 15-19 are rejected as indefinite for the alleged omission of essential steps and the alleged absence of a resolution step. Claim 15 is amended to depend from claim 2 instead of claim 1, and to include a resolution step. No new matter is added into the case by the amendments. Claim 2 sets forth claimed modifications to the native hG-CSF gene in order to provide a modified hG-CSF gene according to one embodiment of the present invention. Presently amended claim 15 sets forth methods used to provide the modified gene segments of claim 2. These methods are further described in Example 1 on pages 13-16 of the specification, and may be used to provide modified segments having the modifications enumerated on pages 9-10 of the specification. Hence, one possessing ordinary skill in the art would immediately understand the scope of the presently amended claims in light of the specification. Accordingly, claims 15-19 are not indefinite.

Claims 20-22 are rejected as allegedly being indefinite, but the reasons are not clearly described in the office action. In any event, claim 20 depends from allowable claim 6, and claims 21 and 22 depend from claim 20. Claim 20 is amended to correct grammatical errors, which are believed to have been the basis for the Examiner's §112 rejection thereof. No new matter is entered into the case by the amendment. Accordingly, since claims 20-22 depend from an allowable claim, and any possible deficiency in claim 20 has been rectified, they should also be deemed compliant with §112.

Reconsideration and allowance of claims 2, 4, and 15-22 are hereby respectfully requested.

C. Claims 2-4, 7, 15, 17, 19, and 20 are Patentable Over the Cited Reference

Claims 2-4, 7, 15, 17, 19, and 20 are rejected as being allegedly anticipated by Hockney. Claim 2 is directed to a modified DNA sequence coding for hG-CSF. According to one preferred embodiment of the invention. Claim 2 comprises a nucleotide sequence which includes sequence segments modified with respect to the native hG-CSF sequence, as specified in the claim as amended. Hockney teaches a process for preparing polypeptides using a modified DNA sequence for hG-CSF in combination with amino acid supplements during fermentation to achieve hG-CSF expression levels of up to 35% of the total microbial protein (Examples 2-3, in columns 5-6 of Hockney). However, Hockney is only able to reach these expression levels by the addition of certain amino acids to the growth media, and not from the sequence modifications called for in claim 2.

Hockney does not disclose a DNA sequence modified as called for in claim 2, therefore it cannot anticipate the claim. For example, Hockney does not disclose replacement of the CGG Arg148 codon in segment III with a CGT Arg148 codon, nor does it disclose replacement of the GGA Gly150 codon in segment III with a GGT Gly150 codon, both of which are called for in claim 2. The failure of Hockney to disclose either of these replacements disqualifies Hockney as an "anticipatory" reference. Hence, the sequence of claim 2 and the sequence taught by Hockney differ by at least these codons, and therefore the sequence claimed in claim 2 is not anticipated by Hockney. It is well established that in order for a reference to anticipate a claim, the reference must contain each and every element and limitation found in the claim. Since Hockney does not disclose the aforementioned limitations of claim 2, the claim is plainly not anticipated by Hockney.

Claims 3, 4, and 7 depend from claim 2 and add further important elements and limitations thereto also not found in or suggested by Hockney. The claims are patentable over Hockney for the same reasons that claim 2 is patentable over the reference, as discussed above.

Claim 15 depends from claim 2, and claims a method of making a novel DNA sequence as called for in claim 2. Claim 2 is not anticipated by Hockney for the reasons discussed above, and thus its dependents are not anticipated. Accordingly, claim 15 should be allowable because the base claim is allowable. Claims 17 and 19 depend from claim 15 and add elements and

limitations thereto. Claims 17 and 19 should be allowable over the reference for the same reasons that claim 15 should be allowable.

Claim 20 depends from allowable claim 6. Therefore, claim 20 should be allowable for the same reasons that claim 6 is allowable. Reconsideration and allowance of claims 2-4, 7, 15, 19, and 20 are hereby respectfully requested.

D. Claims 5, 16, 18, 21, and 22 are Patentably Distinct Over the Cited References

Claims 5, 16, 18, 21, and 22 are rejected as allegedly obvious from Hockney considered in combination with Baneyx. However, for a combination of references to render a claim obvious, the combined references must at least contain all of the elements or limitations in the rejected claim. Plus, it must be shown that it would have been "obvious" for a person of ordinary skill in the art to combine them in the way imagined by the Examiner.

These claims (claims 5, 16, 18, 21, and 22) are all dependent claims, which depend from claims for which there is either no prior art rejection or for which the only art rejection is alleged anticipation based only on the Hockney reference which, as demonstrated above, is not well taken. In an attempt to remedy the recognized deficiencies of Hockney in regard to these dependent claims, Baneyx is combined with Hockney in an effort to show how the subject matter of these claims would have been obvious to a person of ordinary skill in the art. However, the combination of Baneyx and Hockney does not even provide what is called for in claim 2, much less all of the limitations of claim 5. Specifically, Baneyx fails to disclose replacement of the CGG Arg148 codon in segment III with a CGT Arg148 codon, or replacement of the GGA Gly150 codon in segment III with a GGT Gly150 codon as called for in claim 2, from which claim 5 depends. Since the references in combination fall short of disclosing the requirements of claim 2, from which claim 5 depends, they plainly cannot even render the subject matter of claim 5 (which is claim 5 plus claim 2) obvious. Thus, claim 5 is patentable over the combination of references. Furthermore, even if the combination of Hockney and Baneyx disclosed all the requirements of the claims, which it does not, the Examiner has failed to point to any objective evidence of any motivation, teaching, or incentive as to why the person of ordinary skill would put them together in the way claimed by the Applicants or imagined by the Examiner.

Claims 16 and 18 depend from claim 15 and add further elements and limitations thereto, also not disclosed in or obvious from these references. According to the MPEP, if a base claim is

allowable, then all of its dependents are also allowable. Since claim 15 depends from claim 2, which has been shown herein to be patentable over the references cited, then dependent claims 16 and 18 must also be patentable.

Claims 21 and 22 depend from claim 20, which itself depends from claim 6, an allowable claim. Therefore, claims 21 and 22 must be patentable over the cited references.

Reconsideration and allowance of claims 5, 16, 18, 21, and 22 are hereby respectfully requested.

CONCLUSION

Finally, the Examiner contends that the IDS filed on January 31, 2005 fails to comply with 37 C.F.R. 1.98(a)(2) for allegedly failing to provide copies of the non-patent literature listed. Although Applicants respectfully believe their citation of prior art to be compliant under the circumstances (given the citation of the same art in a manner arguably compliant with International rules), a new IDS, copies of the references, and the required fee are nevertheless provided herewith in order to advance prosecution of the case.

Applicants assert that the claims of the present application meet the requirements of 35 U.S.C. §112 and patentably define over the prior art made of record relied upon, as well as that not relied upon, for the same reasons as given above. Applicants respectfully submit that a full and complete response to the office action is provided herein, and that the application is now fully in condition for allowance. Action in accordance therewith is respectfully requested.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 122355.

Respectfully submitted,

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